

## **REMARKS**

In response to the Office Action dated January 18, 2007, claims 53, 56-61 and 74-76 have been amended and new claim 77 has been added. No new matter has been added by way of the amendments. Reexamination and reconsideration of the claims as requested is respectfully requested.

Prior to discussion of the specific rejections, Applicant believes a short summary of the present invention is warranted.

The present invention as claimed evaluates heart rate and the variability thereof using a set of threshold parameters that account for the user's physiological state, including conditions abnormalities and/or idiosyncrasies, transient or not, that affect the heart rate or its variability, present at the time of the test. As a result, the present invention provides an individualized approach based upon the user's current physical status which may change over a small period of time, i.e., minutes, or over a long period of time, i.e., months or years.

Within each stage, i.e., awake, non-REM sleep, or REM sleep, individualized parameters and associated threshold levels are calculated and reflect the individual user's physiological status during the data capture interval. This improved functionality assures that the data is accurate and ensures that the user is not awakened at an inappropriate time due the use of incorrect predetermined parameters and threshold levels.

Applicant disagrees with the Examiner's conclusion that the claim language does not specify that the threshold as claimed must be non-predetermined. The specification is quite clear in a number of places that the "calculated parameters" are defined as being

obtained real time and a “threshold level” is then calculated based upon these calculated parameters. An alternative to this approach is a predetermined set of values.

Notwithstanding Applicant's disagreement with the Examiner on this point, Applicant has amended claim 53 and added claim 77 to expedite prosecution on this matter.

Applicant also disagrees with the Examiner concerning the conclusion that, inter alia, cited references Halyak and Amano teach heart rate variability testing.

Heart rate is simply an absolute value, i.e., 60 beats per minute. Heart rate variability (HRV), on the other hand, is a measurement and quantitation of the variation of the timing between heart beats. HRV may be represented statistically as a standard deviation of the differences in timing between heart beats. There is absolutely no discussion with Halyak and Amano regarding HRV. Halyak discusses, at best, the absolute values around Heart Rate and the changes from timepoint to timepoint, e.g., 60 bpm vs 75 bpm. HRV is a decidedly different measurement than that disclosed by Halyak.

Moreover, Amano describes a device for assessing the circulatory status of a patient using, inter alia, shape analysis of blood pulse waves. The analysis parameters used by Amano are instructive. Four parameters are analyzed, two resistance components, capacitance and inductance. See col. 16, lines 25-39. It is well known in the art that these four parameters are associated with the flow of electricity through the body and more particularly relate to the level of fluid in a circuit represented in this case, by a body. It is very unclear to Applicant how this is associated in any respect with the claimed invention's focus on HRV analysis. Applicant believes that Amano would

simply not be looked to by one skilled in the art and, as a result, is an entirely inappropriate reference in this matter.

In paragraph 6 on page 3 of the Office Action, claims 53-61 and 65-68 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Halyak, et al. (U.S. 5,928,133) in view of Amano, et al. (U.S. 6,126,595). Applicant respectfully traverses this rejection.

Independent claim 53, as amended, makes clear that the present invention as claimed evaluates heart rate and the variability thereof using a set of threshold parameters that account for the user's physiological state, including conditions abnormalities and/or idiosyncrasies, transient or not, that affect the heart rate or its variability, present at the time of the test. As a result, the present invention provides an individualized approach based upon the user's current physical status which may change over a small period of time, i.e., minutes, or over a long period of time, i.e., months or years.

Halyak, by contrast, teaches a threshold that is preselected or predetermined by the user and, by definition, cannot accommodate any physiological conditions, etc., of the user that may affect or impact heart rate or its variability. As a result, Halyak fails to suggest a non-predetermined user selected threshold value. Amano fails to cure Halyak's defects in this regard.

Accordingly, Applicant is of the opinion that independent claim 53 is inventive and not obvious over the art cited by the Examiner.

Applicant respectfully requests the Examiner withdraw the rejection of claim 53 under 35 U.S.C. § 103(a) as being unpatentable over Halyak in view of Amano.

Claims 54-61 and 65-68 are dependent upon independent claim 53, with each claim adding additional limitations. As a result, dependent claims 54-61 and 65-68 are allowable over the cited art.

Accordingly, Applicant respectfully requests the Examiner withdraw the rejection of claims 54-61 and 65-68 under 35 U.S.C. § 103(a) as being unpatentable over Halyak in view of Amano.

In paragraph 20 on page 8, claims 62-64 are rejected 35 U.S.C. § 103(a) as being unpatentable over Halyak, et al. and Amano, et al. as applied to claim 53 above, in view of Golosarksky, et al. (U.S. 5,718,235). Applicant respectfully traverses this rejection.

Claims 62-64 are dependent upon independent claim 53 discussed above in connection with the rejection over Halyak and Amano. Golosarksky fails to cure a primary defect of the combination of Halyak and Amano, that is, Golosarksky fails to disclose a heart rate variability monitor that evaluates heart rate and the variability thereof using a set of threshold parameters that, *inter alia*, accounts for the user's physiological state, including conditions abnormalities and/or idiosyncrasies, transient or not, that affect the heart rate or its variability, present at the time of the test. Thus Applicant asserts that independent claim 53 is not obvious over the combination of Halyak, Amano and Golosarksky. Further, dependent claims 62-64 comprise additional limitations beyond that enumerated within independent claim 53 and, as a result, are allowable over the cited art.

Accordingly, Applicant respectfully requests the Examiner withdraw the rejection of claims 62-64 under 35 U.S.C. § 103(a) as being unpatentable over Halyak, et al. and Amano, et al. as applied to claim 53 above, in view of Golosarksky.

In paragraph 22 on page 8, claims 69-70 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Halyak, et al. and Amano, et al., as applied to claim 54 above, in view of Atlas, et al. (U.S. 6,265,978). Applicant respectfully traverses this rejection.

Claims 69-70 are dependent upon independent claim 53 discussed above in connection with the rejection over Halyak and Amano. Atlas fails to cure a primary defect of the combination of Halyak and Amano, that is, Atlas fails to disclose a heart rate variability monitor that evaluates heart rate and the variability thereof using a set of threshold parameters that, *inter alia*, accounts for the user's physiological state, including conditions abnormalities and/or idiosyncrasies, transient or not, that affect the heart rate or its variability, present at the time of the test. Thus, Applicant asserts that independent claim 53 is not rendered obvious over the combination of Halyak, Amano and Atlas. Further, dependent claims 62-64 comprise additional limitations beyond that enumerated within independent claim 53 and, as a result, are allowable over the cited art.

Accordingly, Applicant respectfully requests the Examiner withdraw the rejection of claims 69-70 under 35 U.S.C. § 103(a) as being unpatentable over Halyak, et al. and Amano, et al. as applied to claim 53 above, in view of Atlas.

In paragraph 25 on page 9, claims 71-73 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Halyak, et al. and Amano, et al., as applied to claim 53

above, in view of Gomes, et al. (U.S. 4,570,637). Applicant respectfully traverses this rejection.

Claims 71-73 are dependent upon independent claim 53 discussed above in connection with the rejection over Halyak and Amano. Gomes fails to cure a primary defect of the combination of Halyak and Amano, that is, Gomes fails to disclose a heart rate variability monitor that evaluates heart rate and the variability thereof using a set of threshold parameters that, *inter alia*, accounts for the user's physiological state, including conditions abnormalities and/or idiosyncrasies, transient or not, that affect the heart rate or its variability, present at the time of the test. Thus, Applicant asserts that independent claim 53 is not rendered obvious over the combination of Halyak, Amano and Gomes. Further, dependent claims 71-73 comprise additional limitations beyond that enumerated within independent claim 53 and, as a result, are allowable over the cited art.

Accordingly, Applicant respectfully requests the Examiner withdraw the rejection of claims 69-70 under 35 U.S.C. § 103(a) as being unpatentable over Halyak, et al. and Amano, et al. as applied to claim 53 above, in view of Gomes.

In paragraph 27 on page 10, claims 74-76 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Halyak, et al. and Amano, et al., as applied to claim 54 above, in view of Lind, et al. (U.S. 6,889,165). Applicant respectfully traverses this rejection.

Claims 74-76 are dependent upon independent claim 53 discussed above in connection with the rejection over Halyak and Amano. Lind fails to cure a primary defect of the combination of Halyak and Amano, that is, Lind fails to disclose a heart

rate variability monitor that evaluates heart rate and the variability thereof using a set of threshold parameters that, *inter alia*, accounts for the user's physiological state, including conditions abnormalities and/or idiosyncrasies, transient or not, that affect the heart rate or its variability, present at the time of the test. Thus, Applicant asserts that independent claim 53 is not rendered obvious over the combination of Halyak, Amano and Lind. Further, dependent claims 74-76 comprise additional limitations beyond that enumerated within independent claim 53 and, as a result, are allowable over the cited art.

Accordingly, Applicant respectfully requests the Examiner withdraw the rejection of claims 74-76 under 35 U.S.C. § 103(a) as being unpatentable over Halyak, et al. and Amano, et al. as applied to claim 53 above, in view of Lind.

### **CONCLUSION**

In view of the amendments and reasons provided above, it is believed that all pending claims are in condition for allowance. The amendments clarify the patentable invention without adding new subject matter. Applicant respectfully requests favorable reconsideration and early allowance of all pending claims.

Authorization is hereby given to charge any additional fees that relate to the filing of this amendment and RCE and are necessary to avoid abandonment of this application to Deposit Account Number 50-1038.

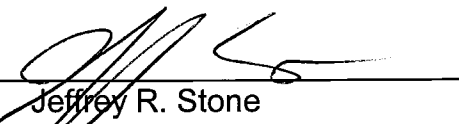
If a telephone conference would be helpful in resolving any issues concerning this communication, please contact Applicant's attorney of record, Jeffrey R. Stone at 952 253-4130.

Respectfully submitted,

Altera Law Group, LLC  
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By:

  
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